Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	
	)	
Amendment of Part 15 of the Commission's	)	
Rules to permit operation of biomedical	)	ET Docket No. 95-177
telemetry devices on VHF TV channels 7-13	)	
and on UHF TV channels 14-46	)	

REPORT AND ORDER
(Proceeding Terminated)

Adopted: October 9, 1997 **Released: October 20. 1997**

By the Commission:

INTRODUCTION

1. By this action, the Commission amends Part 15 of its rules to expand the availability of frequencies and to increase the permitted power for unlicensed biomedical telemetry devices operating on VHF and UHF television channels within health care facilities. These biomedical telemetry devices will provide patients the freedom to move about in a limited area while being continually monitored, speeding patient recovery times, shortening lengths of stay, and reducing health care costs.

2. The standards being adopted for these devices should protect existing television and future advanced digital television (DTV) services and low power television (LPTV) stations from potential interference. The Commission is also implementing a coordination procedure to protect radio astronomy observatories from potential interference from biomedical telemetry devices operating at 608-614 MHz (TV channel 37). These changes support spectrum efficiency by facilitating the sharing of scarce radio spectrum and facilitating use of radio spectrum to provide cost-efficient and needed medical technologies to health care communities.

BACKGROUND

3. Biomedical telemetry devices are used in hospitals to transmit patient measurement data to a nearby receiver, permitting patient mobility and improved comfort. Typical devices include heart, blood pressure and respiration monitors. The use of these devices allows patients to walk around early in their recovery while still being monitored for adverse symptoms. With such devices, one health care worker can monitor several patients remotely, thus decreasing health care costs. Part 15 of the Commission's rules, 47 CFR 15, permits the operation of biomedical telemetry devices in the 174-216 MHz band[1] (VHF TV channels 7-13) with field strengths of 1500 microvolts-per-meter (uV/m), measured at three meters,

[1] *See* 47 CFR § 15.241.

and in the 512-566 MHz band[2] (UHF TV channels 21-29) with field strengths of 200 uV/m, measured at three meters.[3] Biomedical telemetry devices are also authorized at higher power levels in the 450-470 MHz band under Part 90.[4]

4. In a Petition for Rule Making, the Critical Care Telemetry Group (CCTG) requested that the Commission modify the Part 15 rules to allow for the operation of biomedical telemetry devices with power levels not to exceed 5 milliwatts on VHF TV channels in the 174-216 MHz band (TV channels 7-13) and on all UHF TV channels (14-69).[5] CCTG maintained that a serious shortage of usable spectrum has placed at risk the continued viability of medical telemetry services and, in turn, the safety of patients who rely on the interference-free provision of these services. CCTG proposed to implement co-channel separation requirements to eliminate any potential for interference being caused to television reception. It stated that these separation requirements can be implemented by using either frequency-selective devices that are installed by trained persons or fixed-frequency devices that are preset for use in a given area. CCTG added that any interference potential is further reduced by limiting the use of these devices to the premises of health care facilities. Even with the future introduction of DTV, CCTG asserted that useable spectrum would exist in any given area. On December 5, 1995, the Commission adopted a *Notice of Proposed Rule Making* ("*Notice*") in this proceeding addressing the petition from CCTG.[6] The parties filing comments in response to the *Notice* are shown in Appendix A.

DISCUSSION

A. Permitted bands of operation

5. In the *Notice*, the Commission noted that it generally has not permitted the operation of unlicensed Part 15 devices within the television bands. Furthermore, it is in the process of establishing procedures and technical criteria for the introduction of DTV.[7] However, the Commission also recognized the need for additional spectrum for biomedical telemetry devices and indicated that the spectrum

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[2] *See* 47 CFR § 15.209(g)(2).

[3] The Commission believes that no manufacturers currently produce biomedical telemetry equipment for the 512-566 MHz band due to the extremely low emission limits.

[4] *See* 47 CFR §§ 90.27, 90.238 and 90.267. Sections 90.267(a)(5) and 90.267(b)(8) permit hospitals or health care institutions that already hold Part 90 licenses to operate medical devices with output powers up to 20 milliwatts, without additional specific authorization.

[5] CCTG consists of Hewlett-Packard Company Medical Products Group, Marquette Electronics, Inc., Pacific Communications, Siemens Medical Systems, Inc., and SpaceLabs Medical, Inc. Its Petition for Rule Making was filed on December 23, 1994.

[6] *See Notice of Proposed Rule Making*, ET Docket No. 95-155, 11 FCC Rcd 1063 (1996).

[7] The Commission has provided a 6 MHz transitional channel for each existing broadcast station to be used to implement DTV operations and has established a transition period during which broadcasters will continue existing TV operations while the new DTV operations are deployed. *See Sixth Report and Order*, MM Docket No. 87-268, 62 FR 26684, May 14, 1997.

allocated for television broadcast stations may be appropriate for use by biomedical telemetry devices. Accordingly, it proposed to allow biomedical telemetry devices to operate on VHF channels 7-13 (174-216 MHz) and on all UHF channels (470-806 MHz) on a non-interference basis under Part 15 of the rules. Comments were requested on the feasibility of unlicensed biomedical telemetry devices sharing spectrum with TV operations and the Private Land Mobile Radio Services.[8] Comments also were sought on the viability of biomedical telemetry devices sharing UHF channel 37 (608-614 MHz), a band reserved exclusively for radio astronomy.[9] By allowing a broad range of operating frequencies, the Commission indicated that it should be easier for manufacturers and operators to identify and use unoccupied frequencies and, therefore, help reduce any potential interference. Comments were sought on the total amount of spectrum that is needed to support biomedical telemetry devices and whether there may be a range of operating frequencies that may be more favorable than others.

6. *Comments.* CCTG states that there is a need for two to four TV channels (12 to 24 MHz of spectrum) in each major metropolitan area in order to provide approximately 200 to 500 channels of 50 kHz bandwidth for biomedical telemetry devices at each hospital.[10] CCTG also states that TV channel 37, allocated exclusively for radio astronomy applications, is well suited for use by biomedical telemetry on a secondary basis.[11]

7. However, commenters expressed considerable concern regarding the potential impact of biomedical telemetry devices sharing spectrum with the TV broadcast frequencies, especially in light of the forthcoming introduction of DTV. Many of the commenters requested that dedicated spectrum, outside of the TV bands, be set aside for biomedical telemetry devices.[12] For example, the Society of Broadcast Engineers (SBE) states that potentially life-critical biomedical telemetry has no place as a "bottom-of-the-food-chain" Part 15 device; if CCTG needs more spectrum, it should explore bands where such use can occur on a licensed, and therefore protected, basis. The Public Broadcasting Service and the Association of America's Public Television Stations (PBS/APTS) add that it would be a mistake for the Commission to establish a new system in the TV broadcasting spectrum where substantial changes are planned. The Community Broadcasters Association (CBA) states that TV spectrum is a poor environment into which to launch more intensive and higher powered use of critical medical devices on which health and lives will depend.[13] The Center for Devices and Radiological Health of the Food and Drug Administration under the Department of Health and Human Services (CDRH) expressed concern

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[8] The land mobile services, under Part 90 of the rules, are authorized to operate in parts of the 470-512 MHz band, dependent on location. *See* 47 CFR Part 90 Subpart L.

[9] *See* 47 CFR § 73.603(c).

[10] *See* CCTG comments at pg. 4.

[11] *See* CCTG comments at pg. 7

[12] *See*, for example, Capital Cities/ABC (CC/ABC) reply comments at pg. 6, Center for Devices and Radiological Health of the Food and Drug Administration under the Department of Health and Human Services (CDRH) reply comments at pg. 1, KUED comments at pg. 2, Association of Maximum Service Television (MSTV) comments at pg. 5, Public Broadcasting Service and the Association of America's Public Television Stations (PBS/APTS) reply comments at pg. 7, and Society of Broadcast Engineers (SBE) reply comments at pg. 2.

[13] *See* CBA comments at pg. 1.

about the potential for injury to patients that might occur if there is interference between the medical device and the primary licensees, recommending that the Commission grant exclusive licenses to biomedical telemetry devices for the primary use of locally unused TV channels.[14] Even CCTG states that the Commission should consider dedicating spectrum to the exclusive use of medical telemetry after the DTV transition.[15] Other commenters, such as the Leesburg Regional Medical Center[16] and Texas Children's Hospital,[17] are concerned that interference will be caused to biomedical devices from TV signals rather than interference from biomedical devices to TV signals.

8. *Decision.* The Commission continues to believe that the TV broadcast spectrum, including operation on TV channel 37, can support low-powered biomedical telemetry systems. While the *Notice* proposed to permit biomedical telemetry operation over the frequency ranges of 174-216 MHz and 470-806 MHz (TV channels 7-69), we no longer believe that this entire frequency range can be made available. In the DTV *Sixth Report and Order* in MM Docket No. 87-268 the Commission indicated that it plans to reallocate TV channels 52-69 (698 MHz to 806 MHz) to other services.[18] Further, it is undecided at this time whether the Commission will reallocate TV channels 2-6 (54-88 MHz) or TV channels 47-51 (668-698 MHz).[19] Thus, this spectrum no longer appears suitable for assignment to unlicensed biomedical telemetry operation. Contrary to the arguments of SBE, PBS/APTS, CBA and others, we believe that the patient benefits provided from providing additional frequencies for biomedical telemetry devices are of sufficient importance to justify the operation of these products on vacant channels within the TV broadcast bands. Further, biomedical telemetry devices are expensive, complex products that are generally installed by the manufacturer or by a third party working with the manufacturer. In most cases, individual systems must be specifically engineered for each location. We observe that biomedical telemetry systems are very sensitive to interference and are more likely to receive interference on any given channel before causing interference. Because interference to these products could endanger the health and safety of the patients using this equipment, it is expected that health care facilities, in combination with the manufacturers and installers, would expend considerable effort to avoid operating on occupied broadcast channels.[20] As already required under the rules, the operator of a Part 15 device, *e.g.*, a health care facility operating a biomedical telemetry device, must accept whatever level of

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[14] *See* CDRH reply comments at pg. 1-2.

[15] *See* CCTG comments at pg. 6.

[16] *See* Leesburg Regional Medical Center comments at pg. 1.

[17] *See* Texas Children's Hospital comments at pg. 1.

[18] *See the Sixth Report and Order* in MM Docket No. 87-268, *supra* at para. 83. *See also the Notice of Proposed Rule Making* in ET Docket No. 97-157, 62 FR 41012, July 31, 1997, proposing to reallocate TV channels 60 - 69 for public safety use and for other services. *In addition, see* Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 251 (1997), requiring the Commission to reallocate TV channels 52 - 69 for other services. The final reallocation will not be decided until the completion of these rule making proceedings. This final reallocation could impact the frequencies available for biomedical telemetry devices.

[19] *See Sixth Report and Order* in MM Docket No. 87-268, *supra* at para. 83.

[20] For this reason, the Commission is not as concerned that interference will be caused to biomedical telemetry devices, such as would occur should these devices be located too close to a licensed station.

interference is received from other radio operations and is responsible for resolving any harmful interference problems caused by the operation of their device, even if resolving that interference requires that the biomedical telemetry device cease operations. [21] Thus, health care facilities should avoid operating on channels that could cause interference to the reception of TV or land mobile services[22] or that could cause the biomedical telemetry devices to receive interference since such interference problems could result in the health care facilities having to change frequencies, an expensive process if it also requires changes to the antenna design or replacement of the transmission system. Further, unlike other Part 15 products that generally are designed for consumer applications, biomedical telemetry devices are "prescription" devices that would be employed by professional health care providers and primarily by hospitals. Accordingly, the Commission believes that the manufacturers and users of these products would take sufficient steps to ensure that proper operating frequencies are found and employed. However, for additional assurance the Commission will note in the rule section pertaining to these devices the need to avoid interference to the authorized services and to accept interference received from other radio operations.

9. The Commission is not implementing dedicated channels for biomedical telemetry devices at this time. The record in this proceeding is not sufficiently complete to determine which, if any, additional channels should be employed. Dedicated channels can be investigated in future proceedings should the equipment manufacturers and users later determine that additional frequencies, without the potential interference problems associated with operation within the TV broadcast bands, are needed. Accordingly, we are amending the rules to permit the operation of biomedical telemetry devices only in the frequency bands of 174-216 MHz (TV channels 7-13) and 470-668 MHz (TV channels 14-46). We recognize that sufficient TV channels may not be available for biomedical use in all major cities. With regard to the forthcoming introduction of DTV, for some period of time coordination may prove more challenging for biomedical telemetry device users. However, we expect that this will become easier once DTV systems have been implemented and standard analog TV broadcasting is phased out.

B. Technical standards

10. The Commission proposed to allow biomedical telemetry devices to operate, as suggested by CCTG, at transmitter power levels not to exceed 5 milliwatts. However, noting that the Part 15 rules generally are based on measurements of radiated emission field strengths and not on transmitter power, that biomedical telemetry devices may not have a readily accessible antenna port to permit output power measurements, and that transmitter power alone is not sufficient to predict the potential for interference to other users, comments were requested on applying a field strength limit of 200 mV/m, as measured at 3 meters.[23] The Commission also proposed to permit an emission bandwidth of 200 kHz with unwanted emissions appearing outside this bandwidth limited to 150 uV/m at 3 meters.

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[21] *See* 47 CFR § 15.5.

[22] Within certain cities, the Public Land Mobile Radio Service share operation over TV channels 14-20 (470-512 MHz). *See* 47 CFR §§ 90.301-317.

[23] An effective radiated power (ERP) of 5 mW is equivalent to a field strength of 165 mV/m at 3 meters. A field strength of 200 mV/m at 3 m is equivalent to an ERP of 7.3 mW, an increase of 1.64 dB.

11. *Comments.* With one exception, the comments supported the application of a field strength limit of 200 mV/m at 3 m, rather than the use of a transmitter output power limit.[24] The National Association of Broadcasters (NAB), while supporting a standard based on a field strength limit, believes that an unspecified lower field strength limit is necessary to permit biomedical telemetry devices to share the spectrum with VHF and UHF broadcast stations.[25] While the Association for the Advancement of Medical Instrumentation (AAMI) states that 200 kHz bandwidth is sufficient,[26] CCTG states that a 6 MHz emission bandwidth would give medical devices flexibility to operate and coexist with other users and would permit manufacturers to incorporate additional channels in each unit.[27] With regard to the limit on unwanted emissions, CCTG states that 150 uV/m limit is too restrictive and proposes 630 uV/m at 3 m, arguing that a lesser level of attenuation is sufficient for TV broadcast stations under Part 73 of the rules and for LPTV and Low Power Auxiliary Stations (LPAS) operating under Part 74 of the rules.[28] AAMI recommends a level of 1/10th of the fundamental output.[29]

12. *Decision.* The Commission agrees that the designation of a field strength limit is the more desirable method of specifying an output level of a transmitter operating under Part 15. This is so because a limit based on field strength takes into account the gain provided by the antenna, and therefore provides better control of interference potential. The Commission also notes that field strength measurements already must be made on the transmitter to demonstrate compliance with the restricted band limits.[30] Thus, no additional burden would be imposed on the manufacturers of biomedical telemetry devices by specifying the fundamental emission in terms of its field strength.[31]

13. As CCTG has made persuasive arguments that increased power is needed for biomedical telemetry devices. The Commission proposed a limit of 200 mV/m as appropriate based on the 5 mW requested by CCTG and given variations in antennas and equipment design.[32] While NAB expresses its concern that a lower field strength level should be applied to prevent interference to television broadcasts, NAB does not suggest a lower limit. However, the Commission believes that the 200 mV/m limit proposed in the *Notice* can be employed without causing interference to licensed stations provided

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[24] *See* comments of Association for the Advancement of Medical Instrumentation at pg. 2, CCTG at pg. 8, and Consumer Electronics Manufacturers Association (CEMA) at pg. 3.

[25] *See* NAB comments at pg. 6 and 8.

[26] *See* AAMI comments at pg. 2.

[27] *See* CCTG comments at pg. 10 and Appendix A to comments at pg. 9.

[28] *See* CCTG comments at pg. 10, Appendix A to comments at pg. 7-8, and reply comments at pg. 7.

[29] *See* AAMI comments at pg. 2.

[30] *See* 47 CFR § 15.205.

[31] While PBS/APTS state that strict rules must be imposed to prevent installation of alternative antenna systems to improve performance, such rules are already in place in Part 15. *See* PBS/APTS reply comments at pg. 5. *See*, also, 47 CFR § 15.203.

[32] *Notice* at para. 10.

sufficient co-channel separation distances are maintained.[33] It also appears that this field strength level is sufficient to permit a workable biomedical telemetry system within the high background radio frequency noise levels associated with a hospital environment. Accordingly, the Commission is adopting the proposed fundamental limit of 200 mV/m, as measured at 3 meters.

14. The Commission also agrees with CCTG that a 6 MHz bandwidth would give biomedical telemetry devices more operating flexibility, permitting manufacturers to incorporate additional channels in each unit without an increase in interference potential. The limit being adopted for the fundamental emission is based on a quasi-peak field strength measured with a defined bandwidth, resulting in what is equivalent to a spectral power density or field strength per unit bandwidth. Thus, as long as the emission from the biomedical telemetry system meets the field strength limit and is contained within a single TV broadcast channel, its interference potential to the authorized services should be unchanged. We observe that permitting wider bandwidth will provide the flexibility to design systems that make the most efficient use of the spectrum. Accordingly, we are requiring only that the signal may not be wider than the 6 MHz bandwidth of a single TV channel, and that the signal must be contained within a single TV channel.

15. The Commission agrees with AAMI and CCTG that some relaxation can be provided on the limits for unwanted emissions, but it does not agree that the limits on unwanted emissions should be relaxed to correspond to those applied to licensed stations. Unlike Part 15 devices, TV broadcast stations, LPTV and LPAS are licensed by the Commission, are coordinated in frequency and location to prevent interference to co-channel and adjacent channel operations, and are operated at locations known by the Commission.[34] The general emission limits contained in 47 CFR § 15.209 are applied to the unwanted emissions produced by most other Part 15 devices. They were developed with the specific intent of preventing interference to television reception and have proved to be effective in this regard.[35] However, biomedical telemetry devices would be operated within vacant TV channels and there is no reason to require unwanted emissions appearing within those vacant channels to be attenuated to the general limits in Part 15. Any interference would be only to other biomedical telemetry systems.[36] As discussed above, the Commission expects each system to be specifically engineered for the individual health care facility in order to avoid interference not only to authorized services but also to other biomedical telemetry equipment. Thus, the Commission believes that it is necessary to establish a limit on unwanted emissions only outside of the TV channel within which the biomedical telemetry device is operated. These unwanted emissions shall be attenuated to the limits in 47 CFR § 15.209.

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[33] The protection of licensed radio services from interference is discussed later in this Report and Order.

[34] As discussed later, the Commission believes that the attenuation provided by the building in which the biomedical telemetry equipment is located varies and can not be ensured. Thus, no additional attenuation due to installation was incorporated into the interference considerations.

[35] The Commission also continues to believe that unwanted emissions should be reduced to the greatest extent that is economically feasible in order to minimize background noise levels within the radio spectrum.

[36] Thus, it is in the best interest of the operators that the manufacturer attenuate within-channel emissions to the maximum extent possible.

C. Protection of authorized services

16. In order to protect the television broadcast service from interference from Part 15 biomedical telemetry devices, the Commission proposed to adopt the co-channel separation requirements suggested by CCTG. Biomedical telemetry devices would be required to be removed from co-channel television broadcast station transmitters by minimum separation distances, as follows: not less than 107.1 km in Zone I and 131.8 km in Zones II and III for devices using VHF channels 7-13 in the 174-216 MHz band and 113.2 km for devices using UHF channels 14-36 and 38-69 in the bands 480-608 MHz and 614-806 MHz in all Zones.[37] The Commission noted that the proposed separation requirements are very close to those specified for LPAS associated with broadcast stations.[38] Additionally, it noted that LPAS are intended to transmit over distances of approximately 100 meters and are authorized to operate at higher power levels than what was proposed for biomedical telemetry devices.[39] Given the lower operating power of biomedical telemetry devices and shorter transmission distances compared to LPAS, comments were sought on whether the proposed co-channel separation distances are overly restrictive. Additionally, the Commission questioned who would be responsible for ensuring adherence to the separation distance requirement. Since there is no licensee that would be responsible for the installation of the equipment, the Commission proposed, as suggested by CCTG, that the equipment be installed by trained field personnel that would select the appropriate operating frequency for a given location. This would result in the installer and end user being responsible for ensuring that devices are properly deployed according to the separation requirements. In addition, the user would be responsible for resolving any interference that occurs subsequent to installation. Comments also were sought on whether any restrictions were needed to protect adjacent TV channels.

17. The Commission also expressed concern about the interaction of biomedical telemetry devices with LPTV stations. As spectrum is needed for new DTV stations, displaced LPTV stations would be permitted to relocate to other available television channels.[40] This relocation of LPTV stations could directly impact the ability of biomedical telemetry devices to find usable spectrum. Thus, comments were sought on the ability of biomedical telemetry devices to share spectrum with the LPTV service.

18. The Commission noted that any effort to accommodate biomedical telemetry devices in TV spectrum during the DTV transition period would require flexibility that could include the ability to change frequency to avoid interfering with DTV channels. Therefore, it proposed that biomedical telemetry devices be designed to be frequency selective to operate over a given range of television channel

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[37] *See* 47 CFR § 73.609 for the definition of Zones I, II and III.

[38] *See* 47 CFR § 74.802. Examples of low power auxiliary station uses include wireless microphones, cue and control communications and synchronization of TV camera signals.

[39] Under 47 CFR § 74.861(e)(1)(i) and (ii) LPAS are authorized powers up to 50 mW on the VHF TV channels and 250 mW on UHF channels.

[40] *See Second Further Notice of Proposed Rule Making* in MM Docket No. 87-268, at para. 41 and footnote 48.

frequencies.[41] Comments were also requested on whether devices should be required to have a minimum number of channels that could be selected.

19. *Comments.* There were a considerable number of comments regarding potential interference between licensed services using the TV broadcast frequencies and biomedical telemetry devices. CCTG states that the separation distances are highly conservative and are more than adequate to prevent interference.[42] It adds that telemetry receivers are very sensitive and, in most areas, telemetry devices would experience interference at closer distances, thus preventing use of that channel by the telemetry devices.[43] CCTG also states that telemetry signals transmitted inside health care facilities will be sufficiently attenuated by the walls of the buildings so as to assure that there will not be objectionable interference to TV reception outside of the facilities.[44] CCTG adds that manufacturers will work closely with health care institutions to locate suitable frequencies and that health care personnel will have access to lists of available frequencies.[45] Capital Cities/ABC (CC/ABC) indicates that there is a possibility for sharing the VHF band and some sharing of the UHF band at greater co-channel distance separations than those proposed.[46] However, it also adds that this would require prior frequency coordination by the medical telemetry user through the existing broadcast auxiliary frequency coordinator network.[47] NAB adds that sharing of the VHF, and some sharing of the UHF spectrum, with higher power than currently permitted under the rules, though not as high as that proposed, may be possible and practical, provided there are adequate controls to insure co-channel distance separations and frequency coordination with other secondary users.[48] However, controls and accountability must be established for the resolution of interference problems.

20. Texas Children's Hospital states that the deployment of telemetry systems should be restricted in markets where co-channel and adjacent channel TV stations exist.[49] PBS/APTS state that interference

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[41] This proposal was intended to help avoid interference and minimize the economic impact of requiring biomedical telemetry device users to purchase new equipment due to changes in television frequency usage during the DTV transition period.

[42] *See* CCTG reply comments at pg. 2.

[43] *See* CCTG reply comments at pg. 5.

[44] CCTG claims that signals from the biomedical telemetry transmitters are attenuated by at least 20 dB. *See* CCTG reply comments at pg. 2 and Engineering Statement attached to the reply comments at pg. 1-4.

[45] *See* CCTG reply comments at pg. 5.

[46] *See* CC/ABC reply comments at pg. 7.

[47] The broadcast auxiliary frequency coordinator network reference by CC/ABC is a voluntary group of the SBE. A list of frequency coordinators for different areas is published once a month. The Commission has not received any acknowledgement from SBE that it agrees to perform this function.

[48] *See* NAB comments at pg. 6.

[49] *See* Texas Children's Hospital comments at pg. 2.

to adjacent TV channels and UHF taboo[50] problems are not addressed.[51] The Consumer Electronics Manufacturers Association (CEMA) also states that the issue of interference to UHF taboo channels is not addressed.[52]

21. CCTG indicates that medical devices and LPAS can coexist using real-time frequency coordination, even in instances when a film crew is operating near a hospital.[53] This drew strong opposition from CC/ABC, PBS/APTS and SBE. CC/ABC states that it fails to see why licensed, fee-paying Part 74 operators should be required to take on the responsibility and added cost of coordinating with unlicensed Part 15 operators.[54] PBS/APTS point out that coordination, especially the real time coordination suggested by CCTG, would be difficult given that there will be no database of biomedical telemetry devices that an LPAS licensee could consult to identify occupied frequencies.[55] SBE proposes a minimum separation distance of 80 km to LPAS, TV translator, TV booster or LPTV stations using coordinates from FCC Form 313.[56] It adds that the suggestion of CCTG that licensed Part 74 broadcast auxiliary stations should protect and be required to provide prior coordination to unlicensed Part 15 devices is ludicrous.[57] SBE also points out that no separation distances were proposed to protect Part 74 licensed services of LPTV, LPAS, TV translators and TV boosters.[58] CBA states that the LPTV industry will be more seriously affected than the full power TV industry if higher powered devices are permitted.[59] It adds that the risk of future difficulty is compounded by the fact that biomedical devices would be unlicensed, so there would be no database to help locate sources of interference, and there would be no way to contact all users to warn them of the risk of interference received when DTV operations start or LPTV stations change channels.

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[50] In addition to co-channel and adjacent channel interference concerns, it is possible for television broadcast stations operating on certain other combinations of channels, principally in the UHF band, to interfere with one another. The frequency allotment constraints on these combinations are known as UHF taboos.

[51] *See* PBS/APTS reply comments at pg. 3.

[52] *See* CEMA comments at pg. 1.

[53] *See* CCTG comments at pg. 9.

[54] *See* CC/ABC reply comments at pg. 5.

[55] *See* PBS/APTS reply comments at pg. 5.

[56] *See* SBE comments at pg. 4. SBE believes it would be realistic to expect conformance of separation distances by licensed Part 90 users and recommends that CCTG file a petition for rule making to permit the operation of biomedical telemetry devices under Part 90. *See* SBE comments at pg. 5.

[57] *See* SBE reply comments at pg. 1.

[58] *See* SBE comments at pg. 3.

[59] *See* CBA comments at pg. 2-3.

22. With regard to installation by trained personnel, CC/ABC is skeptical of the reliability of "trained personnel."[60] SBE seriously questions whether trained field personnel would have the necessary knowledge to ensure proper spacing requirements.[61] PBS/APTS state that the rule language in the item does not propose any specific requirements for installers.[62]

23. With regard to equipment frequency selection capability, CCTG opposes requiring frequency selection; adding that since the market will demand frequency selection, a rule mandating a specific level of selection capability is unnecessary.[63] CCTG states that if this requirement is retained, then the Commission should only require a range of 12 MHz since the TV adjacent channel rules would ensure the availability of spectrum.

24. Finally, CCTG indicates that TV Channel 37 is well suited for use by medical telemetry on a secondary basis, and that telemetry devices can be located approximately 13 km from a radio astronomy facility and provide adequate interference protection to that facility.[64] While formal comments were not received on this issue, the Commission staff contacted Dr. Thomas Gergely, Electromagnetic Spectrum Manager, National Science Foundation, for additional information.[65] Dr. Gergely recommended that protection be provided to the radio astronomy observatories shown in 47 CFR § 2.106, footnote US 311. Based on the 200 mV/m limit being adopted, he stated that protection should include an exclusion zone of 50 miles radius around the Arecibo and Green Bank observatories and around the VLA near Socorro, New Mexico along with an exclusion zone of 20 miles radius around the 10 Very Long Baseline Array (VLBA) stations.

25. *Decision.* Upon further reflection, we no longer believe that the separation distances proposed in the *Notice* are accurate for preventing interference problems between biomedical telemetry devices and TV broadcast operations. Indeed, these proposed separation distances were designed for the purpose of allocating TV broadcast channels. The Commission even recognizes in its rules that these distances will not always prevent interference.[66] The actual minimum separation distances for the purpose of avoiding interference should be based on antenna height, power, frequency and terrain roughness factors of the individual broadcast stations. Further, the proposed separation distances addressed only interference protection to television broadcast stations. However, protection from potential harmful interference from biomedical telemetry devices must be provided to all authorized operations within the TV bands, including TV broadcast stations operating under Part 73 of the rules, Low Power TV, TV Translator and TV Booster Stations operating under Subpart G of Part 74 of the rules, Low Power Auxiliary Stations (LPAS) operating under Subpart H of Part 74 of the rules, and Private Land Mobile

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[60] *See* CC/ABC reply comments at pg. 6.

[61] *See* SBE comments at pg. 4.

[62] *See* PBS/APTS reply comments at pg. 4.

[63] *See* CCTG comments at pg. 6.

[64] *See* CCTG comments at pg. 7 and Appendix A of comments at pg. 9-10. CCTG based its calculated distance on the protection criteria proposed to be applied on TV broadcast stations to radio astronomy sites.

[65] A copy of Mr. Gergely's comments have been placed in the docket file for this proceeding.

[66] *See* 47 CFR § 73.612(a).

Radio Services operating under Part 90 of the rules.

26. The minimum separation distances employed for the purpose of avoiding interference need to be established based on the protection criteria for the individual services. The protection criteria for television reception requires that the field strength of an undesired signal be at least 45 dB less than the broadcast signal. For the purpose of accepting LPTV applications, TV broadcast signals and associated TV booster stations are protected to the broadcast stations' Grade B field strength contours.[67] LPTV stations and TV translator stations are protected at a different field strength contour.[68] Similar protection contours are not provided for LPAS or land mobile stations. However, most LPAS and land mobile stations employ frequency modulation and operate at higher power than biomedical telemetry devices, reducing the distance necessary to protect against interference from biomedical telemetry devices. We believe that it is more likely that LPAS and land mobile stations would cause interference to biomedical telemetry devices than it is that biomedical telemetry devices would cause interference to these operations. We also point out that interference analyses should not generally rely on assumptions about the attenuation of intervening walls and other objects. Biomedical telemetry transmitters are intended to be used on ambulatory patients who could be near windows that offer little or no shielding. Patients could also be immediately outside of the hospital walls, such as on an attached patio.[69] Also, the interference analyses should not rely on assumptions about attenuation due to body shielding. The Commission notes that manufacturers often request that measurements of body-worn transmitters be made while the transmitter is on a person so that any absorption or attenuation of the transmission signal due to the proximity of the person is taken into account.

27. Based on the above, the Commission has recalculated the minimum separation distances necessary to prevent interference to the licensed radio services using TV channels 7-46. Biomedical telemetry devices must be located outside the Grade B field strength contours of co-channel TV broadcast stations and associated TV booster stations by at least 10.3 km for TV channels 7-13 and 5.5 km for TV channels 14-46.[70] Similarly, biomedical telemetry transmitters must be located outside the protected contours of co-channel LPTV and TV translator stations by at least 5.1 km on channels 7-13 and 3.1 km on channels 14-46.[71] The Commission is adopting these minimum separation distances. Minimum

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[67] *See* 47 CFR § 74.705(a). These contours are 56 dBuV/m for TV channels 7-13 and 64 dBuV/m for TV channels 14-46. *See* 47 CFR § 73.683(a).

[68] The protected field strength contours for LPTV and TV translator stations are 68 dBuV/m for channels 7-13 and 74 dBuV/m for channels 14-46. *See* 47 CFR § 74.707.

[69] Only in cases where the biomedical telemetry device would only be located in the interior area of a health care facility could building shielding effects be considered.

[70] Biomedical telemetry transmitters are being authorized to radiate at a level of 200 uV/m, *i.e.*, 106 dBuV/m, as measured at a distance of 3 meters. In order to maintain a signal-to-interference ratio of at least 45 dB, the fundamental emissions from the biomedical telemetry transmitters must be reduced to no greater than 11 dBuV/m for TV channels 7-13 and 19 dBuV/m for TV channels 14-46. The calculated distances in the text are based on the F(50,10) field strength charts, figures 10a and 10c, contained in 47 CFR § 73.699 with the biomedical telemetry transmitter located at a height of 30 meters. The F(50,10) charts are used to predict interference potential whereas the F(50,50) charts are used to predict station coverage.

[71] These calculated distances are based on the F(50,10) field strength charts, figures 10a and 10c, contained in 47 CFR § 73.699 with the biomedical telemetry transmitter located at a height of 30 meters.

separation distances are not being specified for LPAS and land mobile stations, but we are referencing in the rules that biomedical telemetry devices must be sufficiently removed from these stations so as not to cause harmful interference. We believe that these separation criteria are more representative of what is necessary to prevent biomedical telemetry devices from causing harmful interference to the authorized radio services operating within the TV broadcast bands. We also believe that these separation distances may, in many instances, be less than the separation distances originally proposed in the *Notice*.

28. The Commission does not agree with the comments that separation distances are necessary for adjacent channel systems since the emissions from biomedical telemetry devices falling within adjacent channels must comply with the general emission limits in 47 CFR § 15.209, levels that have already proven to be effective in preventing interference. Further, the Commission does not believe that interference problems would occur to UHF taboo channels due to the low signal levels emitted from the biomedical telemetry transmitters.

29. We also do not believe that it is necessary to establish rules mandating that biomedical telemetry devices be frequency selective and be installed by "trained field personnel." Due to the high cost of the equipment, the need for engineering studies to determine appropriate operating frequencies for each location, and the potentially disastrous impact on patient health should the biomedical telemetry systems be installed without properly addressing all interference concerns, the Commission can not conceive that any reputable health care facility would install this equipment without using highly skilled installation personnel. Further, due to the upcoming changes in the operating frequencies of broadcast and LPTV stations, it is likely that manufacturers would incorporate some method to change the operating frequency of their equipment.

30. The Commission wishes to emphasize that Part 15 devices, including biomedical telemetry devices, operate on a sufferance basis. Regardless of the purpose for which the Part 15 devices are used, they are not protected from interference and any interference problems caused to authorized radio operations must be corrected. It is the operator of the product, *i.e.*., the health care facility, that is ultimately responsible for correcting any interference problems, even if correcting the interference requires that the operator cease operation.[72] Specifically, biomedical telemetry devices operating under Part 15 must not cause interference to any of the authorized operations within the TV bands, including TV broadcast stations operating under Part 73 of the rules, Low Power TV, TV Translator and TV Booster Stations operating under Subpart G of Part 74 of the rules, Low Power Auxiliary Stations operating under Subpart H of Part 74 of the rules, and land mobile stations operating under Part 90 of the rules.

31. With regard to operation on TV channel 37, the Commission recognizes that most radio astronomy operations generally are located in rural areas where demand for biomedical telemetry devices is least. However, there may also be circumstances where there is a need for biomedical telemetry devices to be operated on TV channel 37 near such observatories. The Commission also recognizes that it may be possible to locate channel 37 biomedical telemetry devices relatively close to radio astronomy observatories due to specific operating conditions, such as terrain shielding. This is a matter that must be addressed on a case-by-case basis. Accordingly, the Commission is amending its rules to require that the user and installer of a biomedical telemetry device operating on TV channel 37 (608-614 MHz) that is located within 32 km of any of the VLBA radio astronomy sites or within 80 km of any of the other radio astronomy observatories noted in 47 CFR § 2.106, footnote US 311, must coordinate with, and obtain the written concurrence of, the director of the affected radio astronomy observatory before the equipment can be installed or operated. The National Science Foundation point of contact for

[72] *See* 47 CFR § 15.5, particularly § 15.5(c).

coordination is: Spectrum Manager, Division of Astronomical Sciences, NSF Rm 1045, 4201 Wilson Blvd., Arlington, VA 22230; tel: (703) 306-1823.

D. Location of operation

32. When the Commission authorized the operation of biomedical telemetry devices in the 512-566 MHz band (TV channels 21-29), it restricted the use of these devices to hospital buildings.[73] In the *Notice*, the Commission proposed to permit the operation of biomedical telemetry devices in hospitals and other health care facilities. The Commission also noted that health care facilities may include nursing homes and assisted living facilities that may be located in residential neighborhoods and expressed concern about interference that could occur in these residential neighborhoods. Thus, comments were sought on the impact of extending the operation of biomedical telemetry devices to health care facilities.

33. *Comments.* NAB states that the record does not support the operation of telemetry devices outside of hospitals.[74] SBE opposes allowing devices to operate outside of hospitals or ambulances.[75] CCTG states that devices should be permitted in "critical care facilities" whether or not they are hospitals.[76] CCTG adds that the definition of a health care facility must be broad enough to ensure the availability of telemetry devices to a wide range of health care providers and points out that the devices are "prescription" devices and are not available to the public.[77]

34. *Decision.* The Commission agrees that the operation of these biomedical telemetry devices should be expanded to include operation within any health care facilities. The definition of a health care facility includes: hospitals and other establishments that offer services, facilities, and beds for use beyond 24 hours in rendering medical treatment and institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including governmental entities and agencies for their own medical activities.[78] As long as the frequencies of the biomedical telemetry devices are chosen with sufficient care to avoid interference problems to television reception and with limits that are being established herein for unwanted emissions, there should not be any increased interference potential even if the equipment is located near a residential environment. However, the Commission sees no need to permit these products to be located within an ambulance or other moving vehicle. In an ambulance, there would be no method to ensure that a sufficient separation distance from co-channel broadcast operations is maintained. Further, there does not appear to be any need to use a wireless biomedical telemetry system, designed to allow a patient mobility, within an ambulance.

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[73] *See* 47 CFR § 15.209(g)(2).

[74] *See* NAB comments at pg. 14.

[75] *See* SBE comments at pg. 6.

[76] *See* CCTG reply comments at pg. 6.

[77] *See* CCTG comments at pg. 12.

[78] This definition is based on the eligibility requirements for obtaining a license in the Private Land Mobile Radio Services as a Medical Service under Part 90 of the rules. *See* 47 CFR § 90.35(a)(1), (a)(2), and (a)(7).

E. Miscellaneous issues

35. The CDRH stated that the increase in power for telemetry devices may cause interference to other older medical devices that do not meet the voluntary electromagnetic compatibility immunity standards.[79] Thus, it recommends that the biomedical telemetry devices include a warning that there is an increased possibility of interference to other nearby medical devices. While the Commission is sympathetic to the concerns expressed by the CDRH, it notes that this is not a new problem. Older medical devices already are experiencing electromagnetic compatibility problems from cellular telephones and other nearby radio frequency devices. The Commission believes that the health care facilities are already familiar with this type of problem and will consider it when the individual biomedical telemetry systems are engineered for use at their locations.

36. In addition to the new rules being adopted in this Report and Order, the Commission is retaining the existing standards for the operation of biomedical telemetry devices within the 174-216 MHz band (TV channels 7-13).[80] At the lower signal level currently permitted, operation is not restricted to health care facilities and coordination requirements with the authorized radio services using this band are minimal. Further, this lower signal level may eliminate the need to change operating frequencies as DTV and LPTV stations change frequencies. Thus, the Commission sees no reason to delete this existing standard. The Commission is, however, deleting the standard in 47 CFR § 15.209(g)(2) that permitted biomedical telemetry devices to operate under the general limits on TV channels 21-29. It appears that no one has manufactured equipment for this application and that this rule is no longer necessary due to the expanded applications being adopted herein.

PROCEDURAL MATTERS

Final Regulatory Flexibility Analysis

37. As required by Section 603 of the Regulatory Flexibility Act, 5 U.S.C. § 603 (RFA), Initial Regulatory Flexibility Analysis (IRFA) was incorporated into the *Notice of Proposed Rule Making* ("*Notice*") in ET Docket No. 95-177.[81] The Commission sought written public comments on the proposals in the *Notice* including the IRFA. The Commission's Regulatory Flexibility Analysis (FRFA) in this Report and Order conforms to the RFA, as amended by the Contract with America Advancement Act of 1996 (CWAAA), Public Law No. 104-121, 110 Stat. 847 (1996).[82]

1. Need for and Objective of the Rule.

38. In this Report and Order, the Commission amends Part 15 of its rules to expand the availability of frequencies and to increase the permitted power for unlicensed biomedical telemetry devices

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[79] *See* CDRH reply comments at pg. 2.

[80] *See* 47 CFR § 15.241.

[81] Amendment of Part 15 of the Commission's Rules to permit operation of biomedical telemetry devices on VHF TV channels 7-13 and on UHF TV channels, 11 FCC Rcd 1063 (1996).

[82] Subtitle II of the CWAAA is "The Small Business Regulatory Enforcement Fairness Act of 1996" (SBREFA), codified at 5 U.S.C. § 601 *et seq.*

operating on VHF and UHF television channels 7-46 within health care facilities. These devices will provide patients the freedom to move about in a limited area while being continually monitored, speeding patient recovery times, shortening lengths of stay, and reducing health care costs. The changes to the regulations support spectrum efficiency by facilitating the sharing of scarce radio spectrum between two services and providing cost-efficient and needed medical technologies to health care communities.

2. Summary of Significant Issues Raised by the Public Comments in Response to the Initial Regulatory Flexibility Analysis.

39. No comments were received in direct response to the Initial Regulatory Flexibility Analysis. However, commenters expressed considerable concern regarding the potential impact of biomedical telemetry devices sharing spectrum with the TV broadcast frequencies, especially in light of the forthcoming introduction of DTV. Many of the commenters requested that dedicated spectrum, outside of the TV bands, should be set aside for biomedical telemetry devices. For example, the Society of Broadcast Engineers (SBE) states that potentially life-critical biomedical telemetry has no place as a "bottom-of-the-food-chain" Part 15 device; if CCTG needs more spectrum, it should explore bands where such use can occur on a licensed, and therefore protected, basis. The Public Broadcasting Service and the Association of America's Public Television Stations (PBS/APTS) add that it would be a mistake for the Commission to establish a new system in the TV broadcasting spectrum where substantial changes are planned. The Community Broadcasters Association (CBA) states that TV spectrum is a poor environment into which to launch more intensive and higher powered use of critical medical devices on which health and lives will depend. Even CCTG states that the Commission should consider dedicating spectrum to the exclusive use of medical telemetry after the DTV transition. Other commenters, such as the Leesburg Regional Medical Center and Texas Children's Hospital, are concerned that interference will be caused to biomedical devices from TV signals rather than interference from biomedical devices to TV signals.

40. The Critical Care Telemetry Group that petitioned the Commission to implement these rule changes and filed comments in this proceeding consists of Hewlett-Packard Company Medical Products Group, Marquette Electronics, Inc., Pacific Communications, Siemens Medical Systems, Inc., and SpaceLabs Medical, Inc.

3. Description and Estimate of the Number of Small Entities Subject to Which the Rules Apply.

41. For purposes of the Report and Order, the RFA generally defines the term "small business" as having the same meaning as the term "small business concern" under the Small Business Act, 15 U.S.C. § 632, unless the Commission has developed one or more definitions that are appropriate to its activities.[83] Under the Small Business Act, a small business concern is one that: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) meets any additional criteria established by the Small Business Administration (SBA). Since the Regulatory Flexibility Act amendments were not in effect until the record in this proceeding was closed, the Commission was unable to request information regarding the number of small businesses that would be affected by this action. The rules adopted in this Report and Order apply to the operation of unlicensed biomedical telemetry transmitter devices for medical care facilities. These devices are used to transmit data, including heart, blood pressure and respiration monitors, to a nearby receiver.

42. The Commission has not developed a definition of small entities applicable to biomedical telemetry transmitter devices. Therefore, the applicable definition of small entity is the definition under

[83] See 5 U.S.C. § 601(3).

the Small Business Administration (SBA) rules applicable to Communications Services "Not Elsewhere Classified." This definition provides that a small entity is one with $11.0 million or less in annual receipts.[84] According to Census Bureau data, there are 848 firms that fall under the category of Communications Services, Not Elsewhere Classified. Of those approximately 775 reported annual receipts of $11 million or less and qualify as small entities.[85] This category is very broad, and we are unable to determine how many operators of unlicensed biomedical telemetry devices will qualify as small entities.

4. Description of Projected Reporting, Recordkeeping and Other Compliance Requirements.

43. The rule change will not alter current reporting, recordkeeeping or other requirements. To receive equipment authorization to operate on the television channels, applicants would have to demonstrate that their biomedical telemetry devices comply with the equipment standards and obtain an authorization from the Commission.

5. Significant Alternatives and Steps Taken by Agency to Minimize Significant Economic Impact on a Substantial Number of Small Entities Consistent with Stated Objectives.

44. While the *Notice* proposed to permit biomedical telemetry operation over the frequency ranges of 174-216 MHz and 470-806 MHz (TV channels 7-69), we no longer believe that this entire frequency range can be made available. In the DTV *Sixth Report and Order* in MM Docket No. 87-268 the Commission indicated that it plans to reallocate TV channels 52-69 (698 MHz to 806 MHz) to other services and will reallocate either TV channels 2-6 (54-88 MHz) or 47-51 (668-698 MHz).[86] Thus, this spectrum no longer appears suitable for assignment to unlicensed biomedical telemetry operation. Accordingly, we are amending the rules to permit the operation of biomedical telemetry devices only over the frequency bands of 174-216 MHz and 470-668 MHz (TV channels 7-46).

6. Report to Congress.

45. The Commission shall send a copy of this Final Regulatory Flexibility Analysis, along with this Report and Order, in a report to Congress pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. § 801(a)(1)(A). A copy of this FRFA will also be published in the Federal Register.

ORDERING CLAUSES

46. Accordingly, IT IS ORDERED that Part 15 of the Commission's Rules and Regulations IS AMENDED as specified in Appendix B, effective 30 days after publication in the Federal Register. This

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[84] 13 CFR § 121.201, Standard Industrial Classification (SIC) Code 4899.

[85] U.S. Bureau of the Census, U.S. Department of Commerce, 1992 Census of Transportation, Communications, and Utilities, UC92-S-1, Subject Series, Establishment and Firm Size, Table 2D, Employment Size of Firms: 1992, SIC Code 4899 (issued May 1995).

[86] *See the Sixth Report and Order* in MM Docket No.87-268, *supra*. *See also the Notice of Proposed Rule Making* in ET Docket No. 97-157, 62 FR 41012, July 31, 1997, proposing to reallocate TV channels 60 - 69 for public safety use and for other services. *In addition, see* Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 251 (1997), requiring the Commission to reallocate TV channels 52 - 69 for other services.

action is taken pursuant to Sections 4(i), 301, 302, 303(e), 303(f), 303(r), 304, and 307 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307.

47. For further information regarding this Report and Order, contact the Office of Engineering and Technology, John Reed at (202) 418-2455.

FEDERAL COMMUNICATIONS COMMISSION

William F. Caton
Acting Secretary

APPENDIX A

COMMENTING PARTIES

Comments were filed by:

Abbott Northwestern Hospital
American College of Cardiology
American Hospital Association (AHA)
Association for the Advancement of Medical Instrumentation (AAMI)
Association of Maximum Service Television (MSTV)
Cleveland Clinic Foundation
Community Broadcasters Association (CBA)
Consumer Electronics Manufacturers Association (CEMA)
Critical Care Telemetry Group (CCTG)
Health Industry Manufacturers Association (HIMA)
Huntsville Hospital
KUED, Salt Lake City
Lee Memorial Health System
Leesburg Regional Medical Center
Medical College Hospitals (MCH)
National Association of Broadcasters (NAB)
National Electrical Manufacturers Association (NEMA)
Rapid City Regional Hospital
Saint Agnes Medical Center
San Francisco General Hospital
Scott & White Memorial Hospital
Society of Broadcast Engineers (SBE)
Texas Children's Hospital
University of California, Davis
University of California, San Francisco

Reply Comments were filed by:

Albany Medical Center
American Association of Critical-Care Nurses (AACN)
Capital Cities/ABC, Inc. (CC/ABC)
Critical Care Telemetry Group (CCTG)
Deaconess Hospital
Department of Health and Human Services, Center for Devices and Radiological Health of the Food and Drug Administration (CDRH)
Harvard Medical School, Veterans Administration Medical Center
Lakeland Regional Medical Center
Mission St. Joseph's Health System
New England Medical Center
Public Broadcasting Service and the Association of America's Public Television Stations (PBS/APTS)
Rapid City Regional Hospital
St. Agnes Medical Center
St. Margaret Mercy Healthcare Centers
Society of Broadcast Engineers (SBE)

University of California, Los Angeles
University of California, San Francisco
University of Cincinnati Medical Center
University Hospitals of Cleveland
Westchester County Medical Center

APPENDIX B - FINAL RULES

Part 15 of Title 47 of the Code of Federal Regulations is amended as follows:

Part 15 -- RADIO FREQUENCY DEVICES

1. The authority citation for Part 15 continues to read as follows:

AUTHORITY: Sec. 4, 302, 303, 304, 307 and 624A of the Communications Act of 1934, as amended, 47 U.S.C. 154, 302, 303, 304, 307 and 544A.

2. Section 15.205 is amended by adding a new paragraph (d)(5), to read as follows:

§ 15.205 Restricted bands of operation.

* * * * *

(d)(5) Biomedical telemetry devices operating under the provisions of Section 15.242 of this part are not subject to the restricted band 608-614 MHz but are subject to compliance within the other restricted bands.

* * * * *

3. Section 15.209 is amended by deleting paragraphs (g)(1) and (g)(2) and by revising paragraph (g) to read as follows:

§ 15.209 Radiated emission limits; general requirements.

* * * * *

(g) Perimeter protection systems may operate in the 54-72 MHz and 76-88 MHz bands under the provisions of this section. The use of such perimeter protection systems is limited to industrial, business and commercial applications.

4. A new Section 15.242 is added to read as follows:

§ 15.242 Operation in the bands 174-216 MHz and 470-668 MHz.

(a) The marketing and operation of intentional radiators under the provisions of this section is restricted to biomedical telemetry devices employed solely on the premises of health care facilities.

(1) A health care facility includes hospitals and other establishments that offer services, facilities, and beds for use beyond 24 hours in rendering medical treatment and institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including governmental entities and agencies for their own medical activities.

(2) This authority to operate does not extend to mobile vehicles, such as ambulances, even if those vehicles are associated with a health care facility.

(b) The fundamental emissions from a biomedical telemetry device operating under the provisions of this section shall be contained within a single television broadcast channel, as defined in Part 73 of this

chapter, under all conditions of operation and shall lie wholly within the frequency ranges of 174-216 MHz and 470-668 MHz.

(c) The field strength of the fundamental emissions shall not exceed 200 mV/m, as measured at a distance of 3 meters using a quasi-peak detector. Manufacturers should note that a quasi-peak detector function indicates field strength per 120 kHz of bandwidth $\pm$ 20 kHz. Accordingly, the total signal level over the band of operation may be higher than 200 mV/m. The field strength of emissions radiated on any frequency outside of the television broadcast channel within which the fundamental is contained shall not exceed the general limits in Section 15.209.

(d) The user and the installer of a biomedical telemetry device operating within the frequency range 174-216 MHz, 470-608 MHz or 614-668 MHz shall ensure that the following minimum separation distances are maintained between the biomedical telemetry device and the authorized radio services operating on the same frequencies:

(1) At least 10.3 km outside of the Grade B field strength contour (56 dBuV/m) of a TV broadcast station or an associated TV booster station operating within the band 174-216 MHz.

(2) At least 5.5 km outside of the Grade B field strength contour (64 dBuV/m) of a TV broadcast station or an associated TV booster station operating within the bands 470-608 MHz or 614-668 MHz.

(3) At least 5.1 km outside of the 68 dBuV/m field strength contour of a low power TV or a TV translator station operating within the band 174-216 MHz.

(4) At least 3.1 km outside of the 74 dBuV/m field strength contour of a low power TV or a TV translator station operating within the bands 470-608 MHz or 614-668 MHz.

(5) Whatever distance is necessary to protect other authorized users within these bands.

(e) The user and the installer of a biomedical telemetry device operating within the frequency range 608-614 MHz and that will be located within 32 km of the very long baseline array (VLBA) stations or within 80 km of any of the other radio astronomy observatories noted in footnote US 311 of Section 2.106 of this chapter must coordinate with, and obtain the written concurrence of, the director of the affected radio astronomy observatory before the equipment can be installed or operated. The National Science Foundation point of contact for coordination is: Spectrum Manager, Division of Astronomical Sciences, NSF Rm 1045, 4201 Wilson Blvd., Arlington, VA 22230; tel: (703) 306-1823.

(f) Biomedical telemetry devices must not cause harmful interference to licensed TV broadcast stations or to other authorized radio services, such as operations on the broadcast frequencies under Subparts G and H of Part 74 of this chapter, land mobile stations operating under Part 90 of this chapter in the 470-512 MHz band, and radio astronomy operation in the 608-614 MHz band. (See Section 15.5.) If harmful interference occurs, the interference must either be corrected or the device must immediately cease operation on the occupied frequency. Further, the operator of the biomedical telemetry device must accept whatever level of interference is received from other radio operations. The operator, *i.e.*, the health care facility, is responsible for resolving any interference that occurs subsequent to the installation of these devices.

(g) The manufacturers, installers, and users of biomedical telemetry devices are reminded that they must ensure that biomedical telemetry transmitters operating under the provisions of this section avoid operating in close proximity to authorized services using this spectrum. Sufficient separation distance, necessary

to avoid causing or receiving harmful interference, must be maintained from co-channel operations. These parties are reminded that the frequencies of the authorized services are subject to change, especially during the implementation of the digital television services. The operating frequencies of the Part 15 devices may need to be changed, as necessary and in accordance with the permissive change requirements of this chapter, to accommodate changes in the operating frequencies of the authorized services.

(h) The manufacturers, installers and users of biomedical telemetry devices are cautioned that the operation of this equipment could result in harmful interference to other nearby medical devices.